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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,378	08/27/2001	Gust H. Bardy	032580.0017.UTL	2603

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MINNEAPOLIS, MN 55403-2420

EXAMINER
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MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/940,378

Applicant(s)

BARDY ET AL.

Examiner

Kristen Mullen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/17/05 (response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 105, 109-112, 116-119, 121 and 122 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 109-111 is/are allowed.
- 6) ☒ Claim(s) 105, 112, 116-119, 121 and 122 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. The indicated allowability of claims 105, 112, 116, 117, 121 and 122 is withdrawn in view of the newly discovered reference(s) to Trabucco (4,903,699) and Grevis et al. (4,940,054). Rejections based on the newly cited reference(s) follow.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 121-122 are rejected under 35 U.S.C. 102(b) as being anticipated by Trabucco et al. (5,243,977).

With respect to claim 121, Trabucco shows providing electrical pacing stimulus between two implanted electrodes (5 and 2; 505 and 505') disposed exclusive of the heart wherein one of the electrodes is disposed on a canister for an implantable stimulus providing device (Figs. 1, 8, 16; Col. 7, lines 16-36).

Regarding claim 122, Trabucco further shows providing a pair of electrodes outside the patient's vasculature (Fig. 18).

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Again, "exclusive of the heart" has been interpreted as not entering the heart.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 105, 112, 116 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977) in view of Grevis et al. (4,940,054).

Regarding claims 105 and 117, Trabucco shows a method comprising providing a pair of electrodes (5 and 2; 505 and 505') disposed internal to a patient and exclusive of the patient's heart; transferring energy from an energy source to an energy storage system; transferring energy from an energy source (33) to an energy storage system (36); discharging energy from the energy storage system using the electrode pair (5 and 2; 505 and 505') and the pair of electrodes includes a first electrode (5 or 2; 505 or 505') disposed on a stimulus device housing (2; 502) the energy source and the energy storage system (Figs. 1, 8, 16). Although Trabucco fails to specifically teach sensing an event in the patient's cardiac rhythm and determining whether the patient has an abnormally slow heartbeat wherein the step of sensing an event in the patient's cardiac rhythm provides information for determining whether the patient has an abnormally slow heartbeat, attention is directed to Grevis which shows that it is well known in the field of pacemakers to determine whether the patient has an abnormally slow heartbeat based on information provided by sensing an event in the patient's cardiac rhythm in order to detect and treat bradycardia (Fig. 4). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Trabucco to include

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determining whether the patient has an abnormally slow heartbeat based on information provided by sensing an event in the patient's cardiac rhythm as Grevis teaches since it is well known to do this in the field of pacemakers in order to detect and treat bradycardia.

Regarding claim 112, Trabucco further shows the step of implanting the implantable stimulus device includes implanting the stimulus device at approximately the level of the cardiac apex (Fig. 18).

Regarding claim 116, Trabucco further shows providing a pair of electrode outside the patient's vasculature (Fig. 18).

6. Claims 118-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trabucco et al. (5,243,977) in view of Grevis et al. (4,940,054) as applied to claim 117 above and further in view of Bennett et al. (5,331,966). Trabucco and Grevis are as explained before. Although Trabucco and Grevis fail to show the step of determining whether the patient has an abnormally slow heartbeat includes using two sensing electrodes disposed exclusive of the patient's heart and where at least one of the sensing electrodes is not one of the stimulus electrodes, attention is directed to Bennett which teaches an implantable stimulus device with electrodes located on the device housing. Bennett teaches that providing multiple sensing electrodes (A, B, C) on the device housing provides a leadless orientation insensitive means for receiving electrical signals from the heart (Abs). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device housing in the method of Trabucco and Grevis with the device housing of Bennett incorporating sensing electrodes in order to provide a leadless orientation insensitive means for receiving electrical signals from the heart.

The functional language and statements of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art.

Again, "exclusive of the patient's heart" has been interpreted as not entering the patient's heart.

***Allowable Subject Matter***

7. Claims 109-111 are allowed.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Kristen Mullen*

  
Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3762

kdm